DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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October 23, 2015

ArthroCare Corporation
Ashley J. Dawson, PhD
Manager, Regulatory Affairs
7000 West William Cannon Drive
Austin, Texas 78735

Re: K143235
Trade/Device Name: RF20000a Coblation System, RF20000a Controller and FLOW 50 Wand
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 21, 2015
Received: September 23, 2015

Dear Dr. Dawson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143235

Device Name
RF20000a Coblation System:
RF20000a Controller and FLOW 50 Wand

Indications for Use *(Describe)*
Please see attached.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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The RF20000a Coblation System, comprised of the FLOW 50 Wand and the RF20000a Controller, is indicated for the resection, ablation, and coagulation of soft tissues and hemostasis of blood vessels in the following arthroscopic and orthopedic procedures:

	Ablation/Debridement	**Excision/Resection**
All Joints (Hip, Knee, Shoulder, Wrist, Ankle, Elbow)	▪ Articular Cartilage ▪ Bursectomy ▪ Chondroplasty ▪ Fascia ▪ Ligament ▪ Scar Tissue ▪ Soft Tissue ▪ Synovectomy ▪ Tendon	▪ Articular Labrum ▪ Capsule ▪ Cysts ▪ Ligament ▪ Loose Bodies ▪ Plica Removal ▪ Scar Tissue ▪ Soft Tissue ▪ Synovial Membrane ▪ Tendon
Hip		▪ Acetabular Labrum
Knee	▪ ACL/PCL ▪ Notchplasty	▪ Capsular Release ▪ Cartilage Flaps ▪ Discoid Meniscus ▪ Lateral Release ▪ Meniscal Cystectomy ▪ Meniscectomy ▪ Villusectomy
Shoulder	▪ Acromioplasty ▪ Subacromial Decompression	▪ Frozen Shoulder Release ▪ Glenoid Labrum
Wrist		▪ Triangular Fibrocartilage (TFCC)

K143235

510(k) Summary

ArthroCare® Corporation

RF20000a Coblation System: RF20000a Controller with FLOW 50 Wand

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

General Information

Submitter Name:	ArthroCare Corporation
Address	7000 West William Cannon Drive Austin, TX 78735
Contact Person:	Ashley J. Dawson, PhD Manager, Regulatory Affairs Phone: 512-358-5773 Fax: 512-895-1489
Date Prepared:	January 28, 2015

Device Name

Proprietary Name:	RF20000a Coblation System: RF20000a Controller FLOW 50 Wand
Common Name:	Electrosurgical cutting and Coagulation Device and Accessories
Regulation Name:	Electrosurgical cutting and Coagulation Device and Accessories
Regulatory Class:	II
Product Code:	GEI
Regulation Number:	21 CFR 878.4400

Predicate Devices

ArthroCare® System 12000 (Quantum 2)	K082666
ArthroCare ArthroWands® (Ambient Super MultiVac 50)	K083306

Description

RF20000a Coblation System

The RF20000a Coblation System is an electrosurgical system consisting of a bipolar radiofrequency Controller with Integrated Fluid Outflow Regulator; a sterile, disposable, single-use FLOW 50 Wand; and a non-sterile, reusable Foot Control.

This System utilizes bipolar technology specifically designed for the resection, ablation and coagulation of soft tissues and hemostasis of blood vessels in various arthroscopic and orthopedic procedures.

The System offers five distinct Modes of operation: Hi (Ablation), Med (Ablation), Lo (Ablation), Vac (Vacuum), and COAG (Hemostasis). Each Ablation (Coblation) mode allows for precise ablation with minimal damage to surrounding healthy tissue. The COAG mode allows for consistent and precise hemostasis of blood vessels.

FLOW 50 Wand

The FLOW 50 Wand consists of a handle, shaft, integrated cable, and suction tubing. The integrated cable and suction tubing are attached at the proximal end of the handle and connect to the RF20000a Controller and the Fluid Outflow Regulator, respectively. The handle has finger switches that enable Ablation Mode switching (Lo, Med, Hi) as well as activation of the Wand (Vac, Coag, or Ablate). The Foot Control provides an alternate means of controlling these same functions. The Wand is provided sterile and is single-use only.

RF20000a Controller

The RF20000a Controller is designed to deliver radiofrequency energy to the electrodes of the FLOW 50 Wand. The Controller is an enclosed unit with incorporated software that runs both the delivery of radiofrequency energy as well as a Graphical User Interface with which the user can control various modes, levels, volume, etc. Ports for connecting the FLOW 50 Wand and the Foot Control Pedal are located on the front panel.

The Controller incorporates a peristaltic integrated Fluid Outflow Regulator, which provides dynamic control of the rate of removal of conductive irrigating solution and/or fine, less dense, free-floating debris.

Intended Use/Indications for Use

There are no added procedures to the Indications for Use for the subject devices as compared to the predicate Ambient Super MultiVac Wand (K083306) and the Quantum 2 Controller (K082666). However, previously cleared procedures that utilized the Coagulation setting in order to thermally shrink tissue (e.g., Coagulation of Medial Retinaculum) were removed since the FLOW 50 Wand is not designed to be used in that manner. Removal of previously cleared procedures has no effect on the safety and effectiveness of the device when used as labeled.

The RF20000a Coblation System, comprised of the FLOW 50 Wand and the RF20000a Controller, is indicated for the resection, ablation, and coagulation of soft tissues and hemostasis of blood vessels in the following arthroscopic and orthopedic procedures:

	Ablation/Debridement	**Excision/Resection**
All Joints (Hip, Knee, Shoulder, Wrist, Ankle, Elbow)	▪ Articular Cartilage ▪ Bursectomy ▪ Chondroplasty ▪ Fascia ▪ Ligament ▪ Scar Tissue ▪ Soft Tissue ▪ Synovectomy ▪ Tendon	▪ Articular Labrum ▪ Capsule ▪ Cysts ▪ Ligament ▪ Loose Bodies ▪ Plica Removal ▪ Scar Tissue ▪ Soft Tissue ▪ Synovial Membrane ▪ Tendon
Hip		▪ Acetabular Labrum
Knee	▪ ACL/PCL ▪ Notchplasty	▪ Capsular Release ▪ Cartilage Flaps ▪ Discoid Meniscus ▪ Lateral Release ▪ Meniscal Cystectomy ▪ Meniscectomy ▪ Villusectomy
Shoulder	▪ Acromioplasty ▪ Subacromial Decompression	▪ Frozen Shoulder Release ▪ Glenoid Labrum
Wrist		▪ Triangular Fibrocartilage (TFCC)

Summary of Technological Characteristics

The subject devices have the same technological characteristics (i.e., design, material, chemical composition, and energy source) as the predicate devices with the following exceptions (in bold font):

	PREDICATE: **Controller: Quantum 2 (K082666)** **Wand: Ambient Super MultiVac (K083306)**	**SUBJECT:** **Controller: RF20000a** **Wand: FLOW 50**
Intended Use	Resection, Ablation, and Coagulation of Soft Tissue and Hemostasis of Blood Vessels in Arthroscopic and Orthopedic Procedures	Same
Electrical Safety/EMC	IEC 60601-1 Compliant IEC 60601-2-2 Compliant	Same
Controller Specifications/Features		
Input Power	100-240V 50/60Hz	Same
Fuse Rating	8 A	**15 A**
Output Frequency (Fundamental)	100kHz	Same
Default Ablation Set Point / Output Voltage (Vrms)	Set Point 7/ 260	**Med·/ 279**
Ablation Set Point Range / Output Voltage (Vrms)	Set Points 1 to 9/ 100-314	**Lo $^{-}$ to Hi $^{+}$ / 257-340**
Coagulation Set Point Range / Output Voltage (Vrms)	Set Points 1 to 2/65-100	**Coag – Coag Plus/65-85**
Outflow Control Mechanism	Hospital Suction with Roller clamp to adjust flow control. Recommended suction: 200-400 mmHg	**Controller has an integrated low pressure rotational peristaltic pump Range: 0-600 rpm**
Software Program	Software for Quantum 2, V 2.03	**Graphic User Interface V 0.2** **RF controller software for RF20000a, V 1.0**
Weight	<5 kg	**10 kg**
Controller Input Power	442 W (217 ohms)	**460 W (290 ohms)**
Controller Output Power (Ablation, 350 ohm load)	26 – 261 W	**45 -298 W**
Controller Output Power (Coagulation, 350 ohm load)	12 – 27 W	**8 – 30 W**
Controller Crest Factor (350 ohm load)	1.4	Same
Controller Waveforms	Square	Same

	PREDICATE: **Controller: Quantum 2 (K082666)** **Wand: Ambient Super MultiVac (K083306)**	**SUBJECT:** **Controller: RF20000a** **Wand: FLOW 50**
Wand Materials		
Electrode	Tungsten	Same
Shaft	304 Stainless Steel	Same
Outer Shaft Insulation	Black PET Heat Shrink Tubing	**Black Pebax**
Spacer	Ceramic (Alumina)	Same
Adhesive	Epoxy (Loctite 3981)	**Epoxy (Loctite 3984)**
Handle Material	Lexan 104	**Iupilon S3001R**
Wand Suction Line	PVC	Same
Wand Specifications/Features		
Shaft Length	5.34 ± 0.08 inches	**5.31 ± 0.20 inches**
Distal Bend Angle	50°	**40°**
Handle Length	6.03 inches	**6.13 inches**
Number of Electrodes	1 active & 1 return	Same
Number of Internal Suction Ports	2	**1**
Suction	Yes	Same
Shaft Rigid Construction	Yes	Same
Use Limiting Feature	Yes	Yes
Temperature Measure	20 to 60 °C	**10 to 60 °C**
Finger Switch Activation	Yes	Same
Foot Switch Activation	Yes	Same
Software in Wand	No	**Yes**
Packaged Sterile	Yes	Same
Single Use Disposable	Yes	Same
Operates in Conductive Media Environment	Yes	Same
Bipolar/ Monopolar	Bipolar	Same
Sterilization	Radiation	Same
Recommended Active Ablation Time	5 minutes (cumulative ablation) at set point 7	**Lo Mode: 10 minutes** **Med Mode: 4 minutes** **Hi Mode: 2 minutes**
Rated Wand Voltage	320 Vrms	**340 Vrms**
Wand Output Power (Ablation, 350 ohm load)	26 – 255 W	**189 – 298 W**

	PREDICATE: **Controller: Quantum 2 (K082666)** **Wand: Ambient Super MultiVac (K083306)**	**SUBJECT:** **Controller: RF20000a** **Wand: FLOW 50**
Wand Output Power (Coagulation, 350 ohm load)	12 – 27 W	**12 – 21 W**

Substantial Equivalence

Non-clinical performance data such as design verification, software validation, tissue effect testing (histology, thermal margins), and peak temperature testing demonstrated that the subject devices are substantially equivalent to the predicate devices and are safe and effective when used as intended.

Summary

The RF20000a Coblation System is substantially equivalent to the predicate devices. The differences between the ArthroCare RF20000a Coblation System and the predicate devices do not raise any new concerns about the safety or effectiveness of the subject devices.